

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD.,
Plaintiff,

v.

SAREPTA THERAPEUTICS, INC.,
Defendant.

C.A. No. 21-1015 (GBW)

DEMAND FOR JURY TRIAL

SAREPTA THERAPEUTICS, INC. and THE
UNIVERSITY OF WESTERN AUSTRALIA,
Defendant/Counter-Plaintiffs,

v.

NIPPON SHINYAKU CO., LTD. and NS
PHARMA, INC.,
Plaintiff/Counter-Defendants.

**NS'S OPPOSITION TO DEFENDANTS' MOTION FOR
PARTIAL SUMMARY JUDGMENT NO. 2 REGARDING LOST PROFITS**

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I. THE COURT SHOULD DENY SAREPTA’S MOTION OF SUMMARY JUDGMENT OF NO LOST PROFITS

Sarepta’s second motion for summary judgment seeks to bar Nippon Shinyaku¹ from recovering compensatory damages it suffered from Sarepta’s sales of its infringing Vyondys53[®] product. Sarepta’s motion is based on the incorrect premise that patentee Nippon Shinyaku seeks [REDACTED] Based on that premise, Sarepta argues that Nippon Shinyaku has failed to establish the “inexorable flow” of [REDACTED]

Sarepta’s argument is incorrect. *First*, Nippon Shinyaku seeks to recover only **its own profits lost** from Sarepta’s infringement—payments that Nippon Shinyaku is [REDACTED] entitled to (and in practice does) receive for [REDACTED] [REDACTED] Viltepso® to the United States market. As Nippon Shinyaku’s expert, Mr. Mark Hosfield, explained, Nippon Shinyaku’s “lost profits damages [are] based on the lost profits [REDACTED]” and does not [REDACTED]. SOF ¶ 13. Thus, contrary to Sarepta’s assertions, Nippon Shinyaku is not a parent seeking to recover its subsidiary’s profits under an “inexorable flow” theory but rather seeks its [REDACTED] rendering Sarepta’s arguments irrelevant. For this reason alone, Sarepta’s motion should be denied.

Second, even if this Court were to apply the “inexorable flow” doctrine, evidence of the [REDACTED]

[REDACTED] is more than sufficient to establish the “inexorable flow” of the damages incurred by Nippon Shinyaku.

¹ Sarepta refers to Nippon Shinyaku as NS Japan in its Motion. D.I. 409 (“Mot.”) at 1.

II. FACTUAL BACKGROUND

Nippon Shinyaku is the exclusive supplier of Viltepso[®] to the United States [REDACTED]

[REDACTED]
[REDACTED] SOF

¶ 4. *See, e.g.*, D.I. 426-1 (Ex. 53) NS00036893 at 97 ([REDACTED]
[REDACTED]); D.I. 426-1 (Ex. 52)
NS00065827 ([REDACTED]

[REDACTED]
[REDACTED]). Under the [REDACTED]
[REDACTED] Nippon Shinyaku and [REDACTED] Nippon Shinyaku. SOF ¶¶ 6-8.
Nippon Shinyaku [REDACTED] NS Pharma [REDACTED]
[REDACTED], and NS Pharma [REDACTED] [REDACTED] Nippon Shinyaku [REDACTED]
[REDACTED] United States. *Id.* ¶¶ 2-3.

Nippon Shinyaku receives [REDACTED] [REDACTED] NS Pharma
[REDACTED]
[REDACTED] SOF
¶ 9. [REDACTED] *Id.*
(Nippon Shinyaku's [REDACTED]). [REDACTED]
[REDACTED] [REDACTED]
[REDACTED]. *Id.* NS Pharma [REDACTED] Nippon
Shinyaku [REDACTED]. *Id.* ¶ 12.

As Mr. Hosfield explains, [REDACTED] [REDACTED]
[REDACTED]
[REDACTED] SOF

¶ 15. NS Pharma, however, [REDACTED] [REDACTED]
[REDACTED]. *Id.* ¶¶ 5-6.

Consequently, when NS Pharma [REDACTED] [REDACTED] [REDACTED]
[REDACTED] NS Pharma.
SOF ¶ 16.

III. ARGUMENT

Sarepta’s Motion relies on a faulty premise that Nippon Shinyaku seeks to recover [REDACTED]
[REDACTED]. Not true. Nippon Shinyaku seeks to recover its own lost
profits ([REDACTED] due to Sarepta’s infringement, [REDACTED]
profits ([REDACTED])). Relying on its faulty
premise, Sarepta analyzes the “inexorable flow” doctrine, arguing that Nippon Shinyaku cannot
recover lost profits via this doctrine because (1) [REDACTED]
[REDACTED]; and (2) Nippon Shinyaku has not [REDACTED]
[REDACTED]
[REDACTED] but-for world.

Neither argument is meritorious. Sarepta’s motion should be denied.

A. Nippon Shinyaku Seeks Compensation for Damages It Suffers [REDACTED] [REDACTED]

The Patent Act entitles patentees to “damages adequate to compensate for the
infringement.” 35 U.S.C. § 284. Section 284 broadly allows patentees to recover ““any damages’
[they] suffered as a result of the infringement.” *Gen. Motors Corp. v. Devex Corp.*, 461 U.S. 648,
654-55 (1983) (quoting legislative history); *see also Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538,
1544 (Fed. Cir. 1995) (en banc) (“[T]he language of the statute is expansive rather than limiting .
. . providing only a lower limit and no other limitation.”). “The correct measure of damages is a

highly case-specific and fact-specific analysis.” *Mars, Inc. v. Coin Acceptors, Inc.*, 527 F.3d 1359, 1366 (Fed. Cir. 2008). The key question is simply: “[H]ad the Infringer not infringed, what would the Patentee [] have made?” *Rite-Hite*, 56 F.3d at 1545 (quoting *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 507 (1964)).

Patentees that produce the patented item ordinarily seek to recover the profits on sales lost because of the infringement. *Id.* But “lost profits” is not the exclusive damages theory available: Although “patentees tend to try to fit their damages cases into the ‘lost profits’ framework,” “patentees may be entitled to damages above a reasonable royalty on theories entirely distinct from lost profits.” *Mars*, 527 F.3d at 1366.

The record contains ample evidence from which a reasonable jury could conclude that Nippon Shinyaku itself suffered the claimed damages. Sarepta’s motion should therefore be denied.

1. Nippon Shinyaku Seeks to Recover the Profits It Lost Because of Sarepta’s Infringement

Nippon Shinyaku seeks to recover profits that it lost and would have made but for Sarepta’s infringement. Nippon Shinyaku [REDACTED] [REDACTED]

[REDACTED] SOF ¶¶ 2-3, 6-8. The

[REDACTED]

[REDACTED]

Id. ¶ 4. That relationship [REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED] [REDACTED] [REDACTED]

█████ SOF ¶¶ 5-6. Any decrease in █████ due to Sarepta's infringement █████²

SOF ¶ 16; *see also id.* ¶¶ 2-3, 5-8.

As the “goal of lost profits damages is to place the patentee in the same position it would have occupied had there been no infringement,” Nippon Shinyaku is entitled to recover the profits it would have made █████ █████ had Sarepta not infringed. *See Mentor Graphics Corp. v. EVE-USA, Inc.*, 851 F.3d 1275, 1285 (Fed. Cir. 2017).

This case is on all-fours with *In re Biogen '755 Patent Litigation*, No. 10-cv-2734-CCC-JBC, 2018 WL 3586271, at *19 (D.N.J. July 26, 2018). There, patentee Biogen made “intercompany, arm’s length sales to” its subsidiary “in return for payment of an intercompany purchase price.” *Id.* The court found “that the intrafamily, intercompany sales from Biogen to U.S. Corp. can constitute ‘sales’ by Biogen for lost profits purposes.”³ *Id.* In doing so, it noted that the Federal Circuit had “consistently permit[ted] patentees to present market reconstruction theories showing all of the ways in which they would have been better off in the ‘but for world,’ and accordingly to recover lost profits in a wide variety of forms.” *Id.* (quoting *Grain Processing Corp. v. Am. Maize-Prods. Co.*, 185 F.3d 1341, 1350 (Fed. Cir. 1999)).

To the extent Sarepta implies that Nippon Shinyaku must sell directly to end-users in the United States to recover lost profits, (*see* Mot. at 11), it is wrong. Notably, not only does Sarepta

² Even if the events through which Nippon Shinyaku suffered lost profits involved “overseas events” █████ (see SOF ¶ 8), the Supreme Court has held that damages under Section 284 can include “lost foreign profits.” *WesternGeco LLC v. ION Geophysical Corp.*, 138 S. Ct. 2129, 2138 (2018) (holding that although the “legal injury” of infringement must be domestic, damages can include overseas “damages arising from that injury”).

³ Beyond the intercompany sales, Biogen also sought “to recover profits of U.S. Corp.’s sales because those profits flow inexorably to Biogen,” and the court found sufficient record evidence to support such a finding. *Id.*

cite no cases supporting such an assertion, but in *Intuitive Surgical, Inc. v. Auris Health, Inc.*, this Court expressly noted that the approach in *In re Biogen* (i.e., awarding lost profits to the patentee “based on its own lost sales to the related company”) is “consistent with Federal Circuit law.” No. CV 18-1359-MN, 2021 WL 3662842, at *3 n.5 (D. Del. Aug. 18, 2021).

As such, there is ample evidence from which a reasonable jury could find that **Nippon Shinyaku suffered lost profits** because of Sarepta’s infringement. [REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] SOF ¶ 15. As Mr. Hosfield puts it, “[REDACTED]

[REDACTED]

[REDACTED]” SOF ¶ 16; *see also id.* ¶¶ 2-3, 5-8 (explaining how Nippon Shinyaku

[REDACTED]

[REDACTED]).

If Sarepta had not infringed, Nippon Shinyaku would have received [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]. SOF ¶ 15 (describing Mr. Hosfield’s analysis of the but-for world). These damages do

not rest on the [REDACTED] to Nippon Shinyaku—[REDACTED]

[REDACTED]

Sarepta cannot contest that these [REDACTED] [REDACTED]

[REDACTED] The parties c [REDACTED]

[REDACTED]. SOF

¶¶ 7-8. [REDACTED]

[REDACTED] SOF ¶¶ 10-12.

[REDACTED] in the absence of infringement by Sarepta is a classic measurement of lost profits. These [REDACTED] are undoubtedly damages “suffered [by Nippon Shinyaku] as a result of the result of the infringement” and necessary to properly compensate Nippon Shinyaku for Sarepta’s infringement and are recoverable under the Patent Act. 35 U.S.C. § 284; *Gen. Motors*, 461 U.S. at 654-55.

Accordingly, this Court should deny Sarepta’s motion for summary judgment.

B. Summary Judgment Would Also Be Inappropriate Under the “Inexorable Flow” Doctrine

In the alternative, even if Nippon Shinyaku must satisfy the “inexorable flow” doctrine to recover lost profits, the [REDACTED] evidence would allow a reasonable jury to conclude that the lost profits at issue inexorably flow to Nippon Shinyaku.

Sarepta’s argument hinges on mischaracterizing [REDACTED]

[REDACTED]

[REDACTED] Mot. at 10. From there, Sarepta argues that [REDACTED] payments are not recoverable as lost profits (citing only an out-of-circuit district court opinion) and that Nippon Shinyaku has failed to [REDACTED]. *Id.* at 10-13.

At best, these arguments identify facts the jury may weigh in considering damages. Nippon Shinyaku has produced ample contrary evidence showing [REDACTED]

[REDACTED] The Court should therefore deny Sarepta's motion.

1. The “Inexorable Flow” Doctrine Permits Compensatory Damages Based on a Third Party’s Profits that Flow to the Patentee

The “inexorable flow” doctrine is one theory under which lost profits may be awarded. Specifically, this doctrine has been applied in patent infringement cases where a patentee demonstrates through “contractual, structural, or historical” evidence that damages suffered by a related entity are, in effect, “the lost profits of the patentee.” *Polaris Indus., Inc. v. Arctic Cat Inc.*, No. 15-cv-4129 (JRT/TNL), 2019 WL 1118518, at *7 (D. Minn. Mar. 11, 2019); *Schwendimann v. Arkwright Advanced Coating, Inc.*, 220 F. Supp. 3d 953, 974-75 (D. Minn. 2016). The doctrine ensures patentees may recover “‘any damages’ [they] suffered as a result of the infringement.” *Gen. Motors*, 461 U.S. at 654-55.

Courts in this district have twice accepted that Federal Circuit law allows patentees to assert “inexorable flow” theories. *Intuitive Surgical, Inc. v. Auris Health, Inc.*, No. 18-cv-1359-MN, 2021 WL 3662842, at *3 (D. Del. Aug. 18, 2021) (“The Federal Circuit, however, has not foreclosed the possibility that the ‘inexorable flow’ of profits from subsidiary to parent can support a lost profits theory for the two entities collectively.”) (citing *Mars*, 527 F.3d at 1367); *Callaway Golf Co. v. Acushnet Co.*, 691 F. Supp. 2d 566, 575 (D. Del. 2010) (“[W]here the profits of a wholly-owned subsidiary flow up to the parent, inclusion of such profits is appropriate.”) (same).

2. A Reasonable Jury Could Find that Damages Inexorably Flow From NS Pharma to Nippon Shinyaku

If Nippon Shinyaku can only recover lost profits under the “inexorable flow” doctrine, which Nippon Shinyaku disagrees is required (*see supra* Section III.A), there is ample [REDACTED] [REDACTED] from which a reasonable jury could find that the lost profits at issue inexorably flow from NS Pharma to Nippon Shinyaku.

Here, [REDACTED]

[REDACTED]

[REDACTED]. SOF ¶¶ 9, 16. The [REDACTED]

[REDACTED]

[REDACTED] SOF ¶ 11. These [REDACTED]

[REDACTED] *Id.* The record

also includes other [REDACTED] evidence:

[REDACTED]

- [REDACTED] SOF ¶¶ 13-16.

This evidence is more robust than that establishing “inexorable flow” in other cases where Courts have denied summary judgment of no lost profits under the “inexorable flow” doctrine: *Biogen*, *Polaris*, and *Schwendiman*. In *Biogen*, the court held that, based on evidence of “intercompany sales” (for which the court cited no evidence of a contractual relationship), “a rational juror could conclude that the profits of U.S. Corp. flow inexorably to Biogen.” 2018 WL 3586271, at *19. In *Polaris*, the court found genuine disputes of material fact where the patentee’s evidence was a single declaration describing a shared bank account and the patentee’s historical involvement in sales efforts. 2019 WL 1118518, at *8. And in *Schwendiman*, the court found genuine disputes of material fact where patentee’s evidence of inexorability was the related entities’ tax status as wholly-owned “S” corporations. 220 F. Supp. 3d at 975.

Sarepta cites the Federal Circuit’s *Poly-America* and *Mars* decisions (each of which found insufficient evidence of “inexorable flow”), but it makes no effort to compare the evidence in this case to the evidence presented in *Poly-America* and *Mars*. See Mot. at 8-9. There is good reason: Nippon Shinyaku’s evidence far exceeds the evidence in either. In *Poly-America*, the patentee “apparently ha[d] not sold any item on which it claims damages” and sought to establish inexorable flow through generic notions of “share[d] interests” with its sister company “as two entities collaborating in the manufacture and sale” of products. *Poly-America, L.P. v. GSE Lining Tech, Inc.*, 383 F.3d 1303, 1311 (Fed. Cir. 2004). But here, Nippon Shinyaku has not only established that [REDACTED]

[REDACTED]

[REDACTED]

In *Mars*, the patentee sought to rely upon “the parent-subsidary relationship and its consolidated financial statements,” as well as a “traditional royalty-bearing license agreement” that did **not** depend on “whether or not [the subsidiary] made any profit.” 527 F.3d at 1367. This evidence was insufficient for the patentee to recover the subsidiary’s profits under an inexorable-flow theory.⁴ Nippon Shinyaku, in contrast, [REDACTED]

[REDACTED]

[REDACTED]

SOF ¶ 9.

Likewise, Sarepta’s reliance on *Intuitive Surgical* is misplaced. There, the patentee failed to produce evidence “distinguish[ing] the lost profits” of the patentee and its subsidiary until after

⁴ Unlike here, the patentee in *Mars* had stipulated it “would not seek ‘any other damages other than lost profits or a reasonable royalty,’” and thus forfeited other compensatory theories. *Id.* at 1366.

discovery. 2021 WL 3662842, at *3 n. 4. Judge Noreika struck that evidence, leaving the patentee with a paragraph from the expert's opening report generically stating his "understanding" as the sole evidence of inexorable flow. *Id.* Here, there is no dispute that Nippon Shinyaku and NS Pharma fully preserved the argument and produced the relevant documents [REDACTED]

[REDACTED] And NS's expert's, Mr. Hosfield's, analysis [REDACTED]

[REDACTED] but "conclusory." *See* Mot. at 12-13. Sarepta levies that accusation by selectively citing his reports and testimony. *Id.* Sarepta neglects to mention Mr. Hosfield's detailed, multi-page overview of [REDACTED]

elsewhere in his opening report. NS Ex. 54 (Hosfield Op. Rpt.) at 23-26. Critically, even Sarepta's expert John Jarosz does not dispute that [REDACTED]

[REDACTED] SOF ¶ 18. He even provides his own competing estimate of Nippon Shinyaku's "lost profit."⁵ *Id.*

Not only is there is sufficient evidence for a reasonable jury to find that [REDACTED]

[REDACTED] but no reasonable jury could find to the contrary. Even if Nippon Shinyaku were required to satisfy the inexorable-flow doctrine, its evidence does so.

3. Sarepta's Tax Argument Is a Red Herring

To avoid the uncontroverted fact that [REDACTED]

[REDACTED] *See* Mot. at 9-13. To do so, Sarepta [REDACTED]

⁵ Mr. Jarosz's purported analysis of "[REDACTED]" merely summarizes case law addressing the "inexorable flow" doctrine. SOF ¶ 18.

[REDACTED] *See id.* There is no merit to these allegations, and at the very most, they raise questions of fact for the jury to resolve.

Any reasonable read [REDACTED]

[REDACTED] *See, e.g.,* D.I. 426-1 (Ex. 53) NS00036893 (recitals stating that “[REDACTED]

[REDACTED]”). For example, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] *See generally id.*; *see also* SOF ¶¶ 3-8 (describing [REDACTED]).

[REDACTED]

[REDACTED] SOF ¶ 9; *see generally* D.I. 426-1 (Ex. 53) NS00036893. This is consistent with [REDACTED]

[REDACTED]

[REDACTED] D.I. 426-1 (Ex. 52) NS00065827 ([REDACTED]

[REDACTED]

[REDACTED]).

Sarepta’s attempts to recharacterize [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]⁶ Mot. at 12-13; D.I. 426-1 (Ex. 53) NS00036893 at 97-98. The record contains no evidence of any [REDACTED]

⁶ This critique is noticeably absent from Mr. Jarosz’s rebuttal. SOF ¶ 19.

[REDACTED] Rather, the record contains ample evidence for a reasonable jury to determine (1) [REDACTED]

As noted above, [REDACTED]

[REDACTED] SOF ¶ 11. These—as well as witness testimony—evidence [REDACTED]

[REDACTED] *Id.*; see also SOF ¶ 20 (confirming that [REDACTED]

[REDACTED]). From those original terms, Mr. Hosfield quantified [REDACTED]

[REDACTED]⁷ SOF ¶ 17.

Sarepta’s reliance on *Fujitsu* to argue that Nippon Shinyaku may not recover payments [REDACTED] is misplaced. See Mot. at 10-12. In *Fujitsu*, the agreement at issue undisputedly and explicitly set “[t]he transfer price . . . [that] Fujitsu Limited argues are ‘profits’ that FNC transfers to Fujitsu Limited,” without reference to any flow of profits. *Fujitsu Ltd. v. Tellabs, Inc.*, No. 09-cv-4530, 2013 WL 2285794, at *7 (N.D. Ill. May 23, 2013). By the patentee’s own admission, that “transfer price” was “manipulate[d] . . . for its corporate benefit” based on “acceptable profitability ranges prescribed by the IRS.” *Id.* But here, [REDACTED]

⁷ It is irrelevant that, in the real world, NS Pharma [REDACTED]

Id.

[REDACTED]

[REDACTED] SOF ¶ 9. And as to the “[REDACTED]

[REDACTED] SOF ¶ 17.

Thus, to the extent the [REDACTED]

[REDACTED] Nippon Shinyaku’s calculation of compensatory damages does not include it.

* * *

Summary judgment of no lost profits is inappropriate. “The correct measure of damages is a highly case-specific and fact-specific analysis.” *Mars*, 527 F.3d at 1366. Nippon Shinyaku “need only show that there was a reasonable probability that the sales would have been made ‘but for’ the infringement.” *Rite-Hite*, 56 F.3d at 1545. And it has produced ample [REDACTED] [REDACTED] evidence that would allow a reasonable jury to conclude that, but for Sarepta’s infringing sales of Vyondys53®, Nippon Shinyaku [REDACTED]

[REDACTED]

Sarepta’s only contrary argument relies on inappropriately drawing inferences against Nippon Shinyaku. Sarepta urges the Court to infer, contrary to [REDACTED]

[REDACTED]

[REDACTED]

Particularly after drawing all reasonable inferences in Nippon Shinyaku’s favor, this Court should deny Sarepta’s motion.

Dated: January 12, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Amy Dudash, certify that on January 12, 2024, I caused a copy of the foregoing document which was filed under seal, to be served via electronic mail on the following counsel of record:

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